Effective doses, guidelines & regulations

Burch, M.D.[1,2]

[1]Australian Water Quality Centre, PMB 3, Salisbury, Adelaide, SA 5108, Australia.
[2]Cooperative Research Centre for Water Quality and Treatment, PMB 3, Salisbury, Adelaide, SA 5108, Australia.

Introduction

There are currently no regulations or guidelines in the US for protecting human health and ecosystem viability from cyanobacterial harmful algal blooms (CHABs) that occur in fresh, estuary, and marine water environments. A number of other countries however have developed regulations or guidelines for cyanotoxins and cyanobacteria in drinking water, and in some cases in water used for recreation and agriculture. The main focus internationally has been upon microcystin toxins, produced by *Microcystis aeruginosa* and *Planktothrix agardhii*. This is because microcystins are widely regarded as the most significant potential source of human injury from cyanobacteria on a world-wide scale. Many international guidelines have taken their lead from the World Health Organization's (WHO) provisional guideline of 1 µg/L for microcystin-LR in drinking-water released in 1998. The WHO guideline value is stated as being 'provisional', because it covers only microcystin-LR, for reasons that the toxicology is limited and new data for toxicity of cyanobacterial toxins are being generated. The derivation of this guideline is based upon data that there is reported human injury related to consumption of drinking water containing cyanobacteria, or from limited work with experimental animals. It was also recognised that at present the human evidence for microcystin tumor promotion is inadequate and animal evidence is limited. As a result the guideline is based upon the model of deriving a Tolerable Daily intake (TDI) from an animal study No Observed Adverse Effects Level (NOAEL), with the application of appropriate safety or uncertainty factors. The resultant WHO guideline by definition is the concentration of a toxin that does not result in any significant risk to health of the consumer over a lifetime of consumption.

Following the release of this WHO provisional guideline many countries have either adopted it directly (e.g. Czech Republic, France, Japan, Korea, New Zealand, Norway, Poland, Brazil and Spain), or have adopted the same animal studies, TDI and derivation convention to arrive at slight variants based upon local requirements. For example, Australia has a guideline for Total Microcystins of 1.3 µg/L, expressed as toxicity equivalents of microcystin-LR. The rationale for this is that blooms of *Microcystis aeruginosa,* which is the most common toxin-producing cyanobacterium in Australia, can contain a wide range of variants of microcystin in varying amounts. In 1999, Canada set a *maximum accepted concentration* (MAC) for microcystin-LR in drinking-water of 1.5 µg/L, and research by Health Canada is also currently addressing the need to comprehensively include other microcystin variants in surveys and in monitoring. Brazilian federal legislation is perhaps the most comprehensive and includes a mandatory standard of 1 µg/L for microcystins (variants not specified), and recommendations are given for saxitoxins (3 µg/L) and for cylindrospermopsin (15 µg/L).

Although guidelines for cyanotoxins and cyanobacterial cell numbers for recreational waters are in place in a number of countries, it is considered that there is currently insufficient information to derive sound guidelines for the use of water contaminated by cyanobacteria or toxins for agricultural production, fisheries and ecosystem protection.

Additional research is required to support guideline development, including whole-of–life animal studies with each of the known cyanotoxins. In view of the animal studies that indicate that microcystins may act as tumor promoters, and also some evidence of genotoxicity and carcinogenicity for cylindrospermopsin, it may be appropriate to carry out whole-of-life animal studies with both toxicity and carcinogenicity as end-points. This paper also considers the suitability of these regulations for the US, including factors that need to be considered for the adoption of regulations, such as surveys and hazard assessments of the occurrence of various toxin types, and the availability of robust analytical methods and toxin standards for assessment and compliance.